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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,196	03/23/2000	ROGER JOHN DALY	1871-129	8868
6449	7590	03/24/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/509,196	Applicant(s) DALY ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final. ✓
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-7, 19-22, 24-29 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7, 19-22, 24-29 and 31-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*Re*

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 5, 19, 20, 22 and 31 have been amended, claim 1 has been cancelled and claims 33-41 have been added as requested in the amendment filed on January 26, 2005. Claims 5-7, 19-22, 24-29 and 31-41 are pending in the instant application.

Claims 5-7, 19-22, 24-29 and 31-41 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on January 26, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 101***

5. Claims 5-7, 19-22, 24-29 and 31-41 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in appropriate sections of previous office actions of record.

Beginning at page 6 of the Response, Applicant submits that Declaration of Dr. Hitoshi filed on February 10, 2003 fully supports the asserted utility of the claimed polynucleotides encoding 2.2412 protein as tumor markers and, therefore, is sufficient to overcome the instant rejection. Applicant further argues that "[t]he claimed polynucleotides are useful for

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distinguishing breast cancer cells from normal breast cells since they encode a 2.2412 domain that binds to Grb7 and Grb14, each of which are known to be differentially expressed in breast cancer cells relative to normal breast cells” (top at page 8) and refers to specific passages of the instant specification, which allegedly contain references to assertion of specific and substantial credible utility of the claimed polynucleotides. Applicant’s arguments have been carefully considered but are not persuasive for reasons fully explained in the previous office actions of record and reasons that follow.

The Examiner maintains the position that the instant specification, as filed provides no disclosure that the instant claimed polynucleotides encoding a polypeptide of SEQ ID NO: 2 could be specifically used as a marker for breast cancer. The information presented in the instant specification, as originally filed is limited to the disclosure that a protein of SEQ ID NO: 1, designated “a candidate effector protein for the Grb7 family of signaling proteins” (top at page 3), was isolated based on its ability to bind to Grb14 protein within yeast two hybrid screen system (see pages 6-10 of the specification). It was further hypothesized that because Grb14 is related to Grb 7 and Grb 7 is differentially expressed in certain human cancers, the protein that binds to Grb14 could be useful as tumor marker (middle at page5, for example). One skilled in the art readily understands that in order to serve as a tumor marker for a particular cancer, a polynucleotide must be expressed at altered levels or forms in tumor tissue as compared to normal tissue. The simple fact that two proteins are capable of binding to each other within experimental model conditions of yeast two hybrid system does not provide substantial evidence to support the practical utility of the claimed polynucleotides as markers for breast cancer. Moreover, the instant specification clearly indicates that 2.2412 protein is expressed “in all

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tissues examined with the exception of the kidney” (middle at page 10), which clearly contradicts the assertion of its specific utility as a marker for cancerous tissue.

Therefore, for reasons fully explained before and reasons presented above, the instant rejection is maintained.

***Claim Rejections - 35 USC § 112***

6. Claims 5-7, 19-22, 24-29 and 31-41 are rejected under 35 U.S.C. 112, first paragraph for reasons of record in appropriate sections of previous communications of record.

7. Claims 5-7, 20, 22, 24-26, 31-36 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 1, 5-7, 20, 22, 24-26 and 28 in appropriate sections of previous office actions of record.

Applicant traverses the rejection on the premises that, first, “[t]he specification provides a correlation between structure of the 2.2412 polypeptide and its function in binding Grb7 and Grb14” (bottom at page 9 of the Response), and further, that “[t]he specification provides adequate description of sequences that can function as probes within the scope of the claims” (middle at page 10). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

As fully explained before, the distinguishing property of the instant invention is based on assertion that 2.2412 polynucleotides can be used as markers for breast cancer. The instant specification provided a written description of the full sequence of 2.2412 polynucleotide of SEQ

ID NO: 1 and failed to describe any other molecular embodiment that lacks the polynucleotide sequence of SEQ ID NO: 1 (such as having 95% identity to SEQ ID NO: 1 or any other claimed fragment of SEQ ID NO: 1), which can be used as a tumor marker. With regards to Applicant's argument about ability of 2.2412 to bind Grb7, there appears to be no identified clear correlation between the structure of 2.2412 associated with binding to Grb7 and being associated with breast cancer. The instant specification fails to provide written description of the claimed molecules, those polynucleotides that have limited structural similarity to the instant disclosed polynucleotide of SEQ ID NO: 1 and could be used as breast cancer markers. There is also no disclosure presented to support a conclusion that regions of 2.2412 protein that define its ability to bind to Grb7 or Grb14 are the same structures that delineate "core" of 2.2412 molecules associated with breast cancer.

The instant situation is directly analogous to that, which was addressed in *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (Fed. Cir. 1991). The court held that:

"A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. See *Oka*, 849 F.2d at 583, 7 U.S.P.Q. 2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision

the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated”.

In the instant case, the specification fails to provide clear description of the claimed molecules as to allow one to distinguish them from other nucleic acids, and, therefore, it could be concluded that at the time of filing Applicant was not in possession of the claimed genus.

### ***Conclusion***

8. No claim is allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

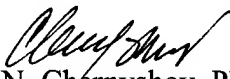
Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1646

March 16, 2005